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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,171	08/31/2004	Kanako Suzuki	040432	5261

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EXAMINER	
HIBBERT, CATHERINE S	
ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,171	SUZUKI ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4,5,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note that the Art Unit information regarding this application has changed. Applicant's Amendments to the Claims, filed 12 September 2007, have been received and entered. Claims 1-19 are pending. Claims 4-5 and 13-14 are withdrawn to non-elected subject matter. Claims 1-3, 6-12, and 15-19 are under consideration in this action.

Response to Arguments

The rejection of claim 7 under ¶ 112(second paragraph) has been withdrawn based on Applicant's Amendments to the Claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and for reasons below.

Applicant's arguments filed 12 September 2007 have been fully considered but they are not persuasive.

Applicants' argument is that claim 11 has been amended to replace "DNA fragment obtained by partial modification of the DNA fragment" with "DNA fragment obtained by substitution or deletion of a part of the base constituting the

DNA fragment, or by addition or insertion of one to several bases," in order to clarify the claim.

Applicants' Amendment to Claim 11 and arguments have been fully considered but are not persuasive because the instant claim, as written, is indefinite with regard to the term "a DNA fragment obtained by substitution or deletion of a part of the base constituting the DNA fragment". For example, it is unclear whether the term "a part of the base constituting the DNA fragment" is referring to an alteration of a *part* of an individual base, such as removal of a methyl or hydroxide group or, alternatively referring to a simple substitution or deletion of a base which is contained in said DNA fragment, and therefore one of ordinary skill in the arts would not be able to determine the metes and bounds of Applicants' invention.

Claim 11 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record and for reasons above.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 11-12, and 15-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Boel et al (US Patent No. 5,536,661: issued 16 July 1996) for reasons of record and below.

Applicant's arguments filed 12 September 2007 have been fully considered but they are not persuasive.

Applicants response is to traverse the rejection because Applicant states that "Claim 1 is directed to a modified promoter constructed by externally inserting a first DNA fragment and a second DNA fragment into a promoter capable of functioning in a filamentous fungus (see, for example, figures 4 and 5)." In addition, Applicant states that although "Boel et al discloses a native TAKA-amylase promoter and a vector carrying functional parts thereof (see, for example, abstract and figure 1)" Applicant argues that "no description regarding a modification of promoter itself is found anywhere in Boel et al., much less the modification of a promoter with a first DNA fragment including CCAATNNNNNN and a second DNA fragment including CGGNNNNNNNNNGG" and Applicant continues that "Boel discloses that promoters may be derived, but this is different than actual base pair modification". Applicant provides examples from the Boel disclosure (col.7, lines 7-12): which recites "suitable promoters may be derived from genes for A. *oryzae* TAKA amylase, *Rhizomucor miehei* aspartic proteinase, *A. niger* giucoamylase [sic], *A. niger* neutral α-amylase, *A. niger* acid stable α-amylase, and *Rhizomucor miehei* lipase". In addition, Applicant recites examples from the Boel disclosure of promoters from genes for glycolytic enzymes, such as TPI, ADH and PGK. But Applicant argues that Boel "does not disclose the modification of promoters in fact", and that therefore "the invention of claim 1 is not legally anticipated by Boel et al".

Applicants' arguments have been fully considered but are not persuasive because the instant claims are directed to a product and not to the process by which the product was made. The MPEP [2113 [R-1]] states that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps". The MPEP states that

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claim 1 is directed to a modified promoter constructed by inserting a first DNA fragment including CCAATNNNNNN (a first base sequence: SEQ ID NO: 1) and a second DNA fragment including CGGNNNNNNNNNGG (a second base sequence: SEQ ID NO: 2) into a promoter capable of functioning in a filamentous fungus. In addition, claim 11, as written, reads very broadly on a modified promoter constructed by integrating a DNA fragment as small as a single nucleotide base (and which has an enhancer function), into a promoter capable of functioning in a filamentous fungus.

Boel et al teaches construction of a vector comprising a "TAKA-amylase promoter or functional parts thereof" for expression of a protein in Aspergillus (see especially abstract, lines 10-13). Boel et al further teaches wherein the promoter contains a first base sequence "CCAATTAGAAG" and a second base sequence "CGGAAATTTAAAGG" that are arranged sequentially from the 5'-end

side to the 3'-end side of said promoter (see especially sequence of Figure 1, lines 17-19 and Boel et al claims 1-4), which meets the limitations of the instant claims 1-3, 6 and 11. Claim 7 is directed to the modified promoter of claim 6, wherein said first DNA fragment and said second DNA fragment are inserted at the 3'-end side that is downstream to a SRE sequence existing in the promoter region. A broad, reasonable interpretation of an "SRE sequence" could read on the nucleotide sequence "5'-ATTTAAAG-3'" which is contained in an SRE consensus sequence (see instant application Seq ID No. 6). Boel et al teaches the sequence "5'-ATTTAAAG-3'" which is upstream to the said first and second DNA sequences and therefore anticipates the limitations of claim 7.

In addition, Boel et al teaches the modified promoter of claim 1, and further teaches wherein said promoter capable of functioning in a filamentous fungus is a promoter of Taka-amylase of Aspergillus oryzae (claim 12). Furthermore, Boel et al teaches a vector in which the modified promoter of claim 1 is integrated (claim 15) and a structural gene of a targeted protein is integrated under control of the modified promoter (claim 16) and further teaches wherein a transformed filamentous fungus comprises the vector and is capable of expressing said structural gene(claims 17-18), and producing a protein by culturing the filamentous fungus of claim 18 under conditions capable of producing protein; and collecting the produced protein (claim 19).

For example, Boel et al recites "the gene for the desired product functionally linked to promoter and terminator sequences may be incorporated in a vector containing the selection marker' or may be placed on a separate vector

or plasmid "capable of being integrated into the genome of the host strain" (col. 12, ¶ 1, lines 1-5). In addition, Boel et al teaches the Taka-amylase promoter and collection of produced protein by accumulation of expressed protein in cells, followed by cell disruption, or preferably, by collection of expressed proteins after proteins are secreted from host cells (col. 11, ¶ 2, lines 1-6 and abstract, lines 1-17 and Boel et al claim 5).

Therefore, Boel et al anticipates the limitations of claims 12 and 15-19.

Claims 1-3, 6-7, 11-12, and 15-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Boel *et al.* for reasons of record and for reasons above.

Claims 7-10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Minetoki et al [("Improvement of promoter activity by the introduction of multiple copies of the conserved region III sequence, involved in the efficient expression of *Aspergillus oryzae* amylase-encoding genes" in Appl Microbiol Biotechnol, 1998:50 p.459-467) made of record in the IDS] for reasons of record and below.

Applicant's arguments filed 12 September 2007 have been fully considered but they are not persuasive.

Applicants response is to traverse the rejection because Applicant states that Claim 7 is directed to a modified promoter, wherein a first DNA fragment and a second DNA fragment are inserted "so that these two sequences are arranged sequentially from the 5'-end side to 3'-end side (see claim 6 from which claim 7

depends)". Applicants further argue that "Minetoki et al disclose a modification of the promoter of agdA gene by inserting the Region III sequence, which includes Regions IIIa and IIIb being arranged sequentially from the 5'-end side to the 3'-end side", and continue that "the Region IIIa and Region IIIb correspond to a second DNA sequence and a first DNA sequence, respectively (See Fig. 1 and p.464, col.2)". Therefore, Applicants submit that "the order of two sequences inserted to modify the promoter in Minetoki *et al* is opposite to that in claim 7" and that "thus, claim 7 cannot legally be anticipated by Minetoki et al".

Furthermore, Applicant argues that the instant claim 8 had been amended to depend from claim 6 and thus renders the rejection of claim 8 and dependent claims 9 and 10 now moot.

Applicants' arguments have been fully considered but are not persuasive because Claim 7 is directed to the modified promoter of claim 6, wherein said first DNA fragment and said second DNA fragment are inserted at the 3'-end side that is downstream to a SRE sequence existing in the promoter region. A broad, reasonable interpretation of an "SRE sequence" could read on the nucleotide sequence "5'-ATTTAAAG-3'" which is contained in an SRE consensus sequence (see instant application Seq ID No. 6).

Minetoki et al teaches wherein a plurality of said first DNA fragments and a plurality of said second DNA fragments are inserted (claim 8), and further to wherein the same number of said first DNA fragments and said second DNA fragments are inserted (claim 9), and further teaches to wherein one first DNA fragment and one second DNA fragment are combined as a pair, and in each

pair, said first DNA fragment and said second DNA fragment are inserted so that the first DNA fragment is located at the 5'-end side of said promoter (claim 10).

For example, Minetoki et al teach modification of the promoter for the *Aspergillus oryzae* amyB gene (see title and abstract). Furthermore, Minetoki et al teach inserting multiple copies of Region IIIa sequence which contains the second base sequence "CGGAAATTTAAAGG" inserted in tandem with the Region IIIb sequence which contains the first DNA fragment including the "CCAATNNNNNN" sequence into the promoter region of a modified vector (see especially Figure & legends 1 and 2). The sequence "CGGAAATTTAAAGG" also reads on a full-length SRE sequence (described above).

More specifically in response to Applicants arguments, it is well taken that the instant claim 6, from which the instant claims 7-10 ultimately depend, limits the claim to wherein the first and second DNA fragment are inserted so that they are arranged sequentially from the 5'-end side to the 3'-end side of said promoter and that the Region IIIa taught by Minetonka et al represents the instant "second DNA fragment" while the Region IIIb taught by Minetonka et al represents the instant "first DNA fragment". However, Minetonka et al clearly teaches wherein the multiple copies of the Region IIIa and IIIb are inserted into the promoter such that , for example, the following DNA fragments are arranged sequentially from the 5'-end side to the 3'-end side of said promoter: Region IIIa, Region IIIb, Region IIIa, Region IIIb, Region IIIa Region IIIb (see p.461, Figure 2). The effect of the multiple copies of the Region IIIa and Region IIIb is that Region IIIb (the

first DNA fragment) is actually arranged sequentially on both sides of the Region IIIa (the second DNA fragment).

Therefore, the Minetoki et al reference meets all of the limitations of the instant claims 7-10.

Claims 7-10 stand rejected under 35 U.S.C. 102(b) as being anticipated Minetoki et al for reasons of record and above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert, Ph.D., whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

Catherine S. Hibbert/AU1636

DAVID GUZO
PRIMARY EXAMINER